PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the **PATENT APPLICATION** of:	
	Loher et al.
Application No.:	08/849,746
Confirmation No:	4225
Filed:	September 5, 1997
For: PROCESS FOR MANUFACTURING COMPONENTS MADE OF FIBER-REINFORCED THERMO-PLASTIC MATERIALS	
Group:	1732
Examiner:	S. Staicovici

Our File: LUD-PT007

Date: June 6, 2005

APPEAL BRIEF

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Brief is submitted within two months of the submission of the Notice of Appeal mailed on April 4, 2005.

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I. Real Party in Interest

The real party at interest is Sepitec Foundation, an entity organized and existing under the laws of Liechtenstein and having its principal place of business at Kirchstrasse 12, Postfach 818, FL-9490 Vaduz, Fürstentum Liechtenstein.

II. Related Appeals and Interferences

There are no appeals or interferences related to this application that will be directly affected by the Board's decision.

III. Status of Claims

Claims 1-14, 16 and 27-31 are pending and all of these claims are appealed. These claims currently stand rejected from an October 4, 2004 non-Final Office Action, which was issued after two rejections and the filing of a Request for Continued Examination. Claims 15 and 17-26 were previously cancelled.

The pending claims are attached in Appendix A.

IV. Status of Amendments

A September 14, 2004 Amendment was the latest amendment entered in this application.

V. Summary of the Invention

The application discloses a process for manufacturing medical components made of fiber-reinforced thermoplastic materials. The process involves forming a blank 7 from fibers and thermoplastic materials that are first pre-finished, and then formed in a negative mold 13, under pressure, in a hot-forming process. See Figure 4, and the accompanying description in the paragraph starting at page 14, line 23. The steps of forming the blank are as follows. First, the blank is heated to a forming temperature with plastic flow consistency in a heating stage located outside the negative mold 13. Second, a pressing head presses the heated blank into the negative mold using a pressing head that travels at a speed of 2mm/sec to 80 mm/sec (see page 14, lines 29-32). Finally, the blank is shaped in the negative mold 13 by virtue of the entire blank flowing from the heating stage into and filling up the negative mold.

VI. Issues

The October 4, 2004 Action rejects all of the claims as obvious over different combinations of references. The Action rejects independent claims 1 and 2 as obvious over two sets of references: (1) over EP 0 373 294 in view of U.S. Patent Nos. 4,356,228 to Kobayashi *et al.* further in view of U.S. Patent No. 4,662,887 to Turner *et al.*; and (2) JP 02-145327 in view of Kobayashi and further in view of U.S.

Patent No. 5,156,588 to Marcune *et al.*

The issue with respect to claims 1 and 2 is whether the combined prior art suggests all of the claimed elements, but in particular, the step of "pressing said heated blank into the negative mold using a pressing head that travels at a speed of 2mm/sec to 80 mm/sec."

The Action rejected the remaining dependent claims as obvious over combinations of EP 0 373 294, JP 02-145327, Kobayashi, Turner, Marcune, WO 91/02906 to Gapp *et al.*, U.S. Patent No. 5,223,526 to Gotoh *et al.*, DE 37 39 294, U.S. Patent No. 5,244,747 to Lee, and JP 01-258918.

In claim 7, the issue is whether EP 0 373 294 and JP 02-145327 show that "the shaping of the blank is accomplished by a push-pull extrusion process," as claimed.

VII. Grouping of Claims

The claims separate into four groupings.

Group 1: claims 1-6, 8-14, 16, and 27-31; and

Group 2: claim 7.

The claim in Group 2 is separated because it does not fall if the claims in Group 1 fall, and because it is believed to be separately patentable from the claims in Group 1. 37 C.F.R. 1.192 (c)7. The claim in Group 2 stands if Group 1 is found to

stand.

VIII. Argument

A. The Obviousness Combination

A combination of references is only proper when there is a suggestion to combine the references and a reasonable expectation of success in combining them. Neither criterion is met here. There is no suggestion within the references themselves for their combination.

The Action combined two groups of references to reject claims 1 and 2. For claim 1, the Action combined EP 0 373 294 in view of U.S. Patent Nos. 4,356,228 to Kobayashi *et al.* further in view of U.S. Patent No. 4,662,887 to Turner *et al.* For claim 2, the Action combined JP 02-145327 in view of Kobayashi and further in view of U.S. Patent No. 5,156,588 to Marcune *et al.*

The proposed combination of axially-pressure formed screw references (EP 0 373 294 and JP 02-145327) with a process of forming sheet material (Kobayashi) for use in medical devices (Turner and Marcune) is unwarranted. At best, the combination of all of these references is a tenuous weave of unrelated references; at worst, the references were cobbled together only after studying the pending claims, and using these claims as a blueprint for the rejections. In either case, the combination is improper.

EP 0 373 294 discloses processes for forming <u>*airplane*</u> screws (Col. 1, lines 8-16.), which ignores the sterility and precision required in medical applications. JP 02-145327 describes a nylon resin and braided yarn reinforced screw that is formed in a mold and axially compressed by a punch. Kobayashi, in contrast, discloses several processes for extruding composite *sheets* for use in "press molding, compression molding, stamping molding," although Kobayashi admits that "[t]he method of molding the preheated sheet is not particularly critical in the present invention." Col. 5, lines 3-4 and 12-13. The mere inclusion of the medical device patents (Turner and Marcune) does not somehow knit together the disparate aircraft, screw, and sheet references into a proper combination.

Why? Because there is no suggestion to combine the aircraft, sheet-forming and medical arts, especially as one of ordinary skill in the art would recognize the shortcomings of using a sheet-forming process in forming precision medical screws. Sheet-forming, using an extrusion or press, would not be practical for use in forming a screw, with its fine threads and engagement surface, and thus would never be consulted to look up a suggested injection molding pressing head speed, as has been done in the Action. Action at page 7.

Further, one of ordinary skill in the art would be hard-pressed to look to the process of forming sheet material (Kobayashi) to yield any expectation of success in the art of screw and screw-thread formation. Since there is no suggestion to

combine the references and no reasonable expectation of success in combining them, the combination is unwarranted and should be withdrawn, together with the accompanying rejections based thereon.

1. The claims in Group 1 (claims 1-6, 8-14, 16, and 27-31) are patentable.

None of the references, alone or in combination, teach "pressing said heated blank into the negative mold using a pressing head that travels at a speed of 2mm/sec to 80 mm/sec." The Action relies on Kobayashi for this teaching, but Kobayashi teaches "closing molds" at 4 mm/sec, which has nothing whatsoever to do with the claimed "pressing head" of the present invention that is used in an injection molding type process to inject the pre-heated blank that is at a plastic flow consistency into a mold cavity. Kobayashi is directed to the compression molding art, would not be proper to consult for an injection molded part because compression molding and injection molding are so different.[1]

Therefore, the rejection of claims 1-6, 8-14, 16, and 27-31 is unwarranted.

2. The claim in Group 2 (claim 7) is patentable.

The Action rejected claim 7, arguing that EP 0 373 294 and JP 02-145327

[1] Compare the descriptions of compression and injection molding in the Modern Plastics Encyclopedia, 1994, enclosed.

teach the claimed push-pull process. Neither reference, in fact, teaches this process. A push-pull process is one in which a thermoplastic is pushed into the mold from a first injection unit, while a second such unit runs in reverse to "pull" the thermoplastic into and through the mold. Then the units both reverse, and the second unit pushes while the first pulls. This yields an extremely uniform part with little or no weld line.[2]

Although the Action argues that EP 0 373 294 and JP 02-145327 show a push-pull process, they do not. EP 0 373 294 shows axially pressing a heated rod into a mold, but it does not teach the "pulling" required in a push-pull process. Similarly JP 02-145327 fails to disclose a "pulling" operation.

Therefore, the rejection of claim 7 is unwarranted.

[2] See, for example, the descriptions of push-pull injection molding enclosed herewith. These are printouts from *The Designer's Guide to Manufacturing*, visited at http://www.designinsite.dk/htmsider/p2007.htm (last visited May 31, 2005).

Conclusion

For the above reasons, Applicants submit that the pending claims are patentable over the prior art. Reconsideration and allowance of the claims is respectfully requested.[3]

Respectfully submitted,

Loher et al.

By______________________
Stephen B. Schott
Registration No. 51,294
(215) 568-6400

Volpe and Koenig, P.C.
United Plaza, Suite 1600
30 South 17th Street
Philadelphia, PA 19103

RJH/SBS/tab

Enclosures:
Appendix A
Modern Plastics Article
Website printout describing push-pull injection moulding

[3] As an aside, Applicant's corresponding European patent EP 0 799 124 B1 has issued both in Europe and several other contries, over art similar to that cited in this Action.

IX. Appendix A (The Pending Claims)

1. A process for manufacturing medical components made of fiber-reinforced thermoplastic materials, where a blank formed of fibers and thermoplastic materials is first pre-finished, and said blank is brought into a final form of a component in a negative mold, under pressure, in a hot-forming process, comprising the steps of:

heating the entire blank to a forming temperature with plastic flow consistency in a heating stage located outside the negative mold,

pressing said heated blank into the negative mold using a pressing head that travels at a speed of 2mm/sec to 80 mm/sec, and

shaping the blank in the negative mold by virtue of the entire blank flowing from the heating stage into and filling up the negative mold.

2. A process for manufacturing medical components which are under stress, made of fiber-reinforced thermoplastic materials, where a blank formed with a fiber proportion of more than 50 volume-% and with at least predominant use of endless fibers and said fiber-reinforced thermoplastic material is first pre-finished, and said blank is brought into a final form of a component in a negative mold, under pressure, in a hot-forming process, comprising the steps of:

heating the entire blank to a forming temperature with plastic flow consistency in a heating stage located outside the negative mold,

pressing said heated blank into the negative mold using a pressing head that travels at a speed of 2mm/sec to 80 mm/sec, and

shaping the blank in the negative mold by virtue of the entire blank flowing from the heating stage into and filling up the negative mold.

3. The process according to Claim 1, wherein the blank is further pre-finished as rod material and is cut to a plurality of lengths required for a final component before the hot-forming process.

4. The process according to Claim 1, further comprising fibers that are endless and have a length that corresponds at least to a length of the blank for a final component.

5. The process according to Claim 1, wherein said blank is composed of layers with different fiber orientation in a lengthwise direction.

6. The process according to Claim 1, wherein the blank is formed from more than one polymer laminate.

7. The process according to Claim 1, wherein the shaping of the blank is accomplished by a push-pull extrusion process.

8. The process according to Claim 1, further comprising the step of:

heating the blank to a forming temperature of 350-450 °C, and then after pressing said blank into the negative mold and shaping thereby,

cooling said shaped blank below the glass transition temperature of the thermoplastic material in a post-pressure phase.

9. The process according to Claim 1, further comprising the step of using carbon or graphite as a release agent for releasing the shaped blank from the negative mold.

10. The process according to Claim 1, wherein the blank is made of PAEK (polyaryl ether ketones) reinforced with carbon fibers.

11. The process according to Claim 1, wherein said blank is formed from endless fibers and at least part of the endless fibers run parallel to an axis of the blank.

12. The process according to Claim 1, wherein at least a portion of the fibers has an orientation from 0 to 90° in the blank.

13. The process according to Claim 1, wherein the fibers have a length of more than 3 mm.

14. The process according to Claim 1, wherein the fibers are surrounded by said thermoplastic material, covering a surface of the blank during said shaping of said blank.

15. (cancelled)

16. The process according to Claim l, wherein the components receive an additional surface seal during the hot-forming process.

17-26. (cancelled)

27. The process according to Claim 7, wherein the reciprocating process is performed more than one time.

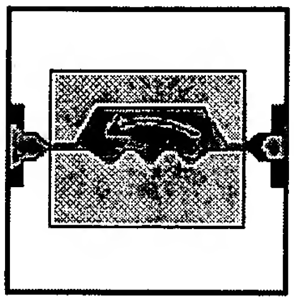
28. The process of claim 1, wherein the blank is rod-shaped.

29. The process of claim 28, wherein the rod-shaped blank is circular in cross-section.

30. The process of claim 2, wherein the blank is rod-shaped.

31. The process of claim 30, wherein the rod-shaped blank is circular in cross-section.

Process Push-pull injection moulding



Suitable for achieving long thin parts with high stiffness in the longitudinal direction. The molecular structure of the parts is very uniform and internal welding lines are reduced.

It is a relatively new variant of injection moulding which improves strength. Unlike injection moulding, two injection units are used for injection of plastic. While one unit is pushing plastic into the mould, the other one is pulling.

First the cavity is filled by the first unit, then pressure and new molten plastic is injected from the second unit to keep the material in motion while it cools down. The process is then reversed.

Danish Name	Push-pull sprøjtestøbning
Category	Mass conserving processes, Shaping plastics
Materials	HDPE PA ABS PC PE PP
Typical products	Window frame for airplane
Competing processes	Injection moulding Air injection moulding Extrusion Pultrusion
Additional info	Possible to achieve good dimensional accuracy and surface finish.
Photo	Thomas Nissen (Computer graphics)
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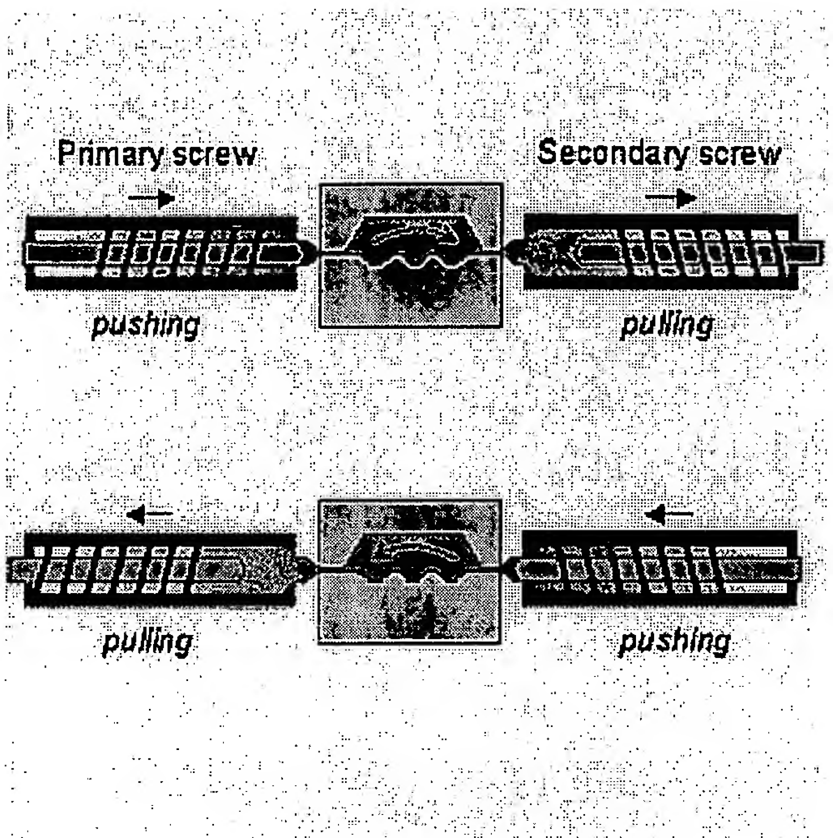
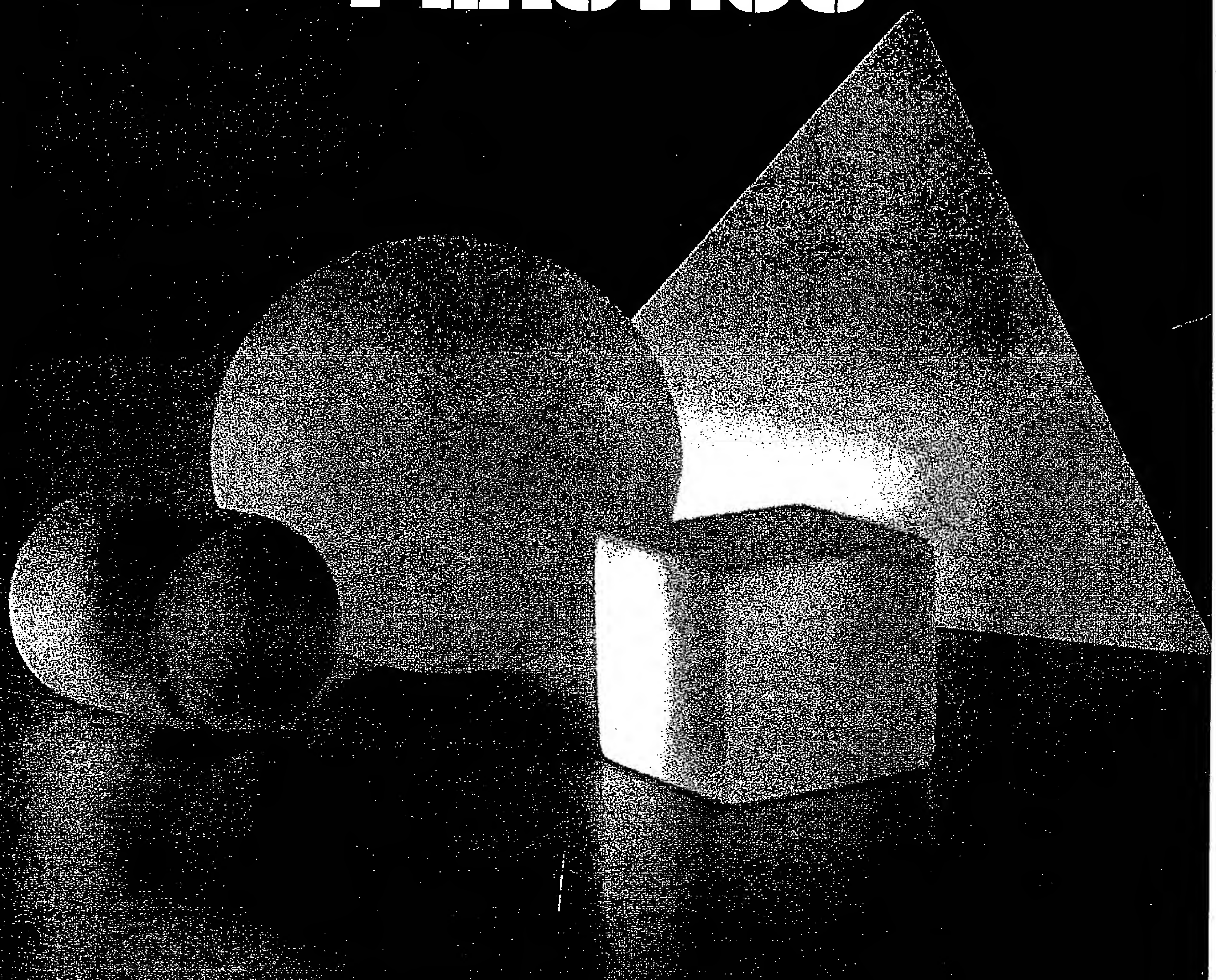


Push-pull injection moulding

Return to
process description

MODERN PLASTICS



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COMPRESSION MOLDING
Low equipment costs and consistency o[f] part sizes are outstanding features

Compression molding dates back hundreds of years to the period when it was used to form objects from amber. The same basic process is used today to produce parts from plastics and elastomers.

Compression molding applies pressure to a material placed inside a heated mold for a specified curing period. Although the procedure is slow—cycle times range from under one minute to 20 min. and more—its simplicity minimizes tooling costs, nearly eliminates material waste, and reduces secondary finishing, and mold wear.

The machinery for compression molding is considerably less expensive than injection molding presses. In addition, compression-molded parts can be fashioned with minimal or zero internal stresses. Consistency of part size is good, and the absence of gate and flow marks in finished products reduces finishing costs.

By Keith A. Larson, Sales Manager, Wabash Metal Products, 1569 Morris St., Wabash, IN 46992.

Compression molding is most cost-effective when u[sed] for short-run parts requiring close tolerances, high imp[act] strength, and low mold shrinkage. Conversely, it is is a p[oor] selection for parts with heavy wall sections requiring lo[ng] cure times, parts with long through-holes, or any sor[t of] large runs. Typical compression-molded parts include g[as]kets, seals, elastomeric bushings, automotive exterior p[an]els, aircraft fairings, control surfaces, and interiors.

Old as the process may be, new applications continu[e to] evolve for compression molding. For example, in the de[ntal] and medical fields, compression-molded orthodontic ret[ain]ers and pacemaker casings are proliferating because of [the] low tool costs. Injection molding tools to produce the sa[me] part would cost as much as eight times more.

Gaskets and seals are examples of products that were o[rig]inally compression molded and were later made by injec[tion] molding to take advantage of the faster cycle times. Howe[ver,] the quality level required for these parts has been hard [to] maintain via injection molding, and many manufacturers [are] now switching back to compression molding.

Like the process, compression-molding machinery is [rel]atively simple. Most compression presses consist of t[wo] platens that close together, applying heat and pressure to [the] material inside.

Mold temperatures typically run between 300 and 400° [F.] but can go as high as 1200° F. The molds are heated by elec[tric] strip heaters, electrical cartridges, steam, or hot-oil systems.

The use of compression molding has expanded trem[en]dously in recent years due to the development of new ma[te]rials, reinforced plastics in particular. Molding reinfor[ced] plastics requires two matched dies usually made of al[u]minum, plastic, or steel. These lightweight materials [are] inexpensive to make and are generally used on short runs.

Though some thermoplastics can be compressi[on] molded, the vast majority of materials used are thermos[ets] such as phenolic, urea, melamine, DAP, epoxy or polyeste[r] in precombined composites such as BMC (bulk moldi[ng] compounds), SMC (sheet molding compounds), or TM[C] (thick molding compounds).

BMC is among the oldest molding systems. A combin[a]tion of fillers—wood flour, minerals, and cellulose—[is] mixed with resin and then placed in a mold at 300 to 400° [F.] and compressed into parts at about 500 p.s.i. Typical appl[i]cations include washtubs, trays, equipment housings, a[nd] electrical components. SMC uses a combination of p[re]impregnated resin fillers, catalysts, and reinforcements, [cut] into part-size sheets or charges, placed in hot molds (usual[ly] 300 to 400° F.), and then molded at 1000 to 2000 p.s.i. Ty[p]ical products include automotive body panels, bathtubs, se[p]tic tanks, and outdoor electrical components.

Another relatively new improvement has been the add[i]tion of various forms of automation to the process. Furth[er] advances in machine and control technology will contin[ue] to make the compression molding process more efficient.

INJECTION MOLDING
Wide array of designs and capabilities make equipment choices complex

The injection molding of thermoplastics is a process in which plastic is melted and then forced into a mold cavity. Once in the mold, the plastic is cooled to a shape reflecting the cavity. The resulting form is usually a finished part needing no other work before assembly or use as a finished product. Details, such as bosses, ribs, designs, and screw threads can be incorporated during the one-step process.

An injection unit and a clamp are the basic elements of all units

Injection molding machines feature two basic components: an injection unit to melt and transfer the plastic into the mold, and a clamp unit to open and close the mold.

The injection unit melts the plastic and then injects it into the mold with controlled pressure and rate. Two basic injection unit designs are used today: the screw preplasticator or two-stage unit, and the reciprocating screw.

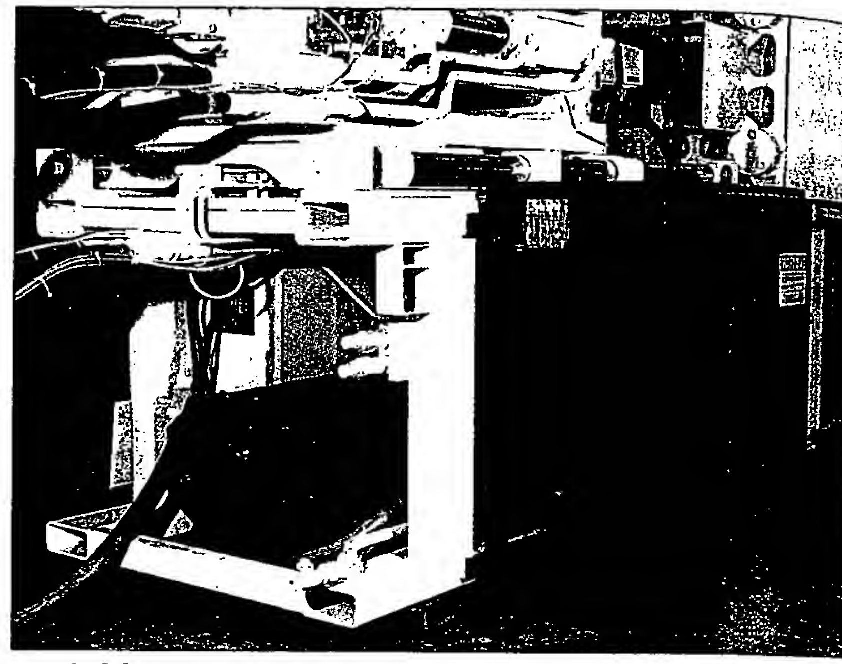
A screw preplasticator uses a plasticating screw (first stage) to feed melted resin into a chamber (second stage). A plunger then forces the plastic melt into the mold. Advantages of the screw-preplasticator are consistent melt quality, high pressures, fast rates, and accurate shot control—benefits useful for clarity, thin-walled parts, and high production rates. Disadvantages include uneven residence time, higher equipment costs, and more maintenance.

The reciprocating screw injection unit, the far more common type, melts and injects the plastic without a plunger. Powdered or pelletized resin is melted in the machine's barrel and transferred to the nozzle end of the machine by a rotating screw. The accumulation of melted plastic at the screw tip forces the screw towards the rear of the machine until enough material is collected for a shot. The screw then is driven forward forcing the melt into the mold.

In reciprocating screw machines, a screw-tip non-return valve is used to prevent material from flowing back along the screw. In recent years, screw-tip non-return valves have been enhanced for a higher degree of part repeatability.

The advantages of reciprocating screw units include reduced residence time, self-cleaning screws, as well as accurate and responsive injection control. These advantages are key to processing heat-sensitive materials, or when making color or resin changes. In addition, reciprocating screws offer repeatable part-to-part consistency and the capability to produce increasingly complex parts with faster cycle times. In addition, closed-loop servovalve control of injection screw velocity and pressure provides repeatable plastic flow into the mold, further improving part-to-part quality. Fast-response servovalve systems also improve processing of parts with complex geometries.

Important factors in plastics processing include temperature and pressure, consistency, color dispersion, and density of the melt. In both types of machines, the polymer is melted by a combination of heated barrels and the shearing action of a rotating screw. Resins, additives, colorants, and fillers are mixed between screw flights and barrel. General purpose screws can process a wide variety of plastic materials. However, special screw designs can optimize the melting and mixing of distinct classes of plastics resulting in improved melt quality, reduced melt temperatures, faster cycle times, and higher production rates.



Variable-speed brushless d.c. motors can provide energy savings in hydraulic injection units. (Photo, Cincinnati Milacron)

Toggle, hydraulic and hydromechanical clamp designs have specific functions

Clamp designs in use today include toggle, hydraulic, and hydromechanical types. Toggle clamps are popular on small-tonnage machines because they are less expensive to manufacture. Features include high mechanical advantage at lockup, inherent built-in clamp slow down, slow mold breakaway speed, and rapid clamp operation. A hydraulic cylinder moves the toggle's crosshead forward, extending the toggle links and moving the platen forward. As the clamp closes, the mechanical advantage is low, resulting in rapid platen movement. As the platen approaches the mold-close position, the toggle links change from a high speed/low mechanical advantage to low-speed and high mechanical advantage.

Low speed is critical for mold protection, while high mechanical advantage is needed to build tonnage. Once the linkage is fully extended locking the mold closed, hydraulic pressure is not needed to hold tonnage. Since the toggle linkage must be at full stroke to achieve tonnage, adjusting the clamp to different mold heights is accomplished by

By Rick Weismantel, Injection Product Specialist, Cincinnati Milacron, 4165 Half Acre Rd., Batavia, OH 45103